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10/566,226	01/27/2006	Gilad Lavi	S2082/20003	3732

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
03/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/566,226	LAVI ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cameron (US Patent No. 5,342,320). Cameron discloses an injection device (Figs. 8-11) comprising: a housing (24) having a proximate end (near 40) and a distal end (near 128), the distal end having an opening therein; a cartridge barrel within the housing (18; please note that the claim language does not currently require that the cartridge barrel be a separate device/not connected to the housing), the cartridge barrel having proximate (near 126) and distal ends (near 102); a needle cannula fixed to the distal end of the cartridge barrel (20); a stopper within the cartridge barrel (76); a driver coupled to the stopper (12); a shield coupled to the housing (30/46/48) and slidable between a retracted (Figs. 8 and 9) and an extended position (Fig. 10); shield driver means activatable to urge the shield from the retracted position to the extended position (106); and sensor means (114) forming a portion of said driver (114 are connected to the driver via attachment area 110) and in slidable contract with an exterior surface of said cartridge barrel (114 slide along the exterior surface of 18), the sensor means arranged to detect an end profile of the barrel and automatically trigger activation of the shield driver means upon detection (Fig. 9 discloses that the end portions of 114 when

they hit the end surface profile of the barrel at 102, they automatically disengage the shield portion 68 and allow the shield to be automatically activated and extended forward around the needles (Figs. 9-10).

In reference to claim 2, Cameron discloses that the shield driver means comprises a coil spring within which the cartridge barrel is located (106).

In reference to claim 3, Cameron discloses that the shield driver means comprises a release mechanism for fixing the spring relative to the driver in a compressed state, the release mechanism being actuable by said sensor means to release the spring (Figs. 8-10).

In reference to claim 4, Cameron discloses that the driver is arranged to be manually pushed through the housing, the driver carrying the shield driver means to a shield activation point (Figs. 8-10).

In reference to claim 5, Cameron discloses that the coil spring is fixed at its proximal end to the driver, and the spring release mechanism fixes the spring to the driver at its distal end (Figs. 8-10).

In reference to claim 6, Cameron discloses that the shield driver means additionally provides a driving force for said driver (Figs. 8-10).

In reference to claim 7, Cameron discloses that the coil spring is fixed at its proximal end to the housing and the spring release mechanism fixes the spring to the driver at its distal end (Figs. 8-10).

In reference to claim 8, Cameron discloses that the sensor means comprises one or more deformable arms attached or formed integrally with the driver (114 are formed integrally with the driver).

In reference to claim 9, Cameron discloses that each arm is biased against the exterior surface of the cartridge barrel and arranged to follow the surface profile of the barrel (Figs. 8-10).

In reference to claim 10, Cameron discloses that the release mechanism comprises a catch provided on a radial outer surface of each deformable arm (Figs. 8-10).

In reference to claim 11, Cameron discloses that the driver and said sensor means are a single molded plastic element (Figs. 8-10).

In reference to claim 18, Cameron discloses that the driver is deformable during assembly (portion 76 is at least deformable and due to catches 120, these portions must also be deformable).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron (US Patent No. 5,342,320) in view of Chevallier (US 2002/0193746). Cameron discloses the device substantially as claimed including an injection device (Figs. 8-11) comprising: a cartridge barrel (18), said barrel arranged to contain a stopper and fluid therein and wherein said barrel has a distal first end (near 132) and a second open end (near 126) and a second end having a radial flange adjacent to the second end (near 124 and 126); a needle cannula (20) having a sharp distal end and a second open end, the fluid being in communication with said needle second end, and wherein said needle second end is coupled at said distal first end; a housing (24) surrounding said barrel, said housing having a distal open end (near 30) adjacent the needle and a proximate end (near 40); a shield (46/48) releasably retained by the housing, said housing and said shield arranged in a sliding relationship with the shield positioned primarily within the housing until release (fig. 8); a driver (12/14), said driver positioned partially within said housing, said driver equipped with at least one deformable side arm (the examiner is interpreting the deformable side arm as being the bottom radially extending flange of the plunger 76, as the plunger is deformable and since the flange

extends radially it could be interpreted as a side arm, and the plunger is part of the driver. Please note that Applicant has not claimed that the side arm must be located outside of the syringe barrel, and Applicant has not claimed any structure regarding the side arm) sensing the distal first end of the barrel (Fig. 9 discloses that the plunger 76 senses the distal end of the barrel when it contacts the barrel. Please note that nothing else regarding "sensing the distal end of the barrel" has been claimed), said driver slidingly located within said housing for moving the stopper forward (Figs. 8-11); and a biasing spring (106), said biasing spring further adapted to bias the shield to automatically cover the needle after said driver detects the end of the barrel (when the plunger hits the end of the barrel as disclosed in Fig. 9, the attached 114 disengage the shield from the catch and allow the spring to bias the shield to cover the needle). Cameron, however, does not disclose that the housing has a flange receiving the radial flange of the barrel. Chevallier, however, discloses a similar injection device (Figs. 1-5) in which a syringe barrel is received within a housing, and the syringe barrel flanges are received on a flange in the proximal end of the housing (Figs. 2, 3 and 5 for example). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Cameron's device by separating the syringe from housing into two components, as taught by Chevallier, as this would only involve separating components, and it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

In reference to claim 13, Cameron discloses that the biasing spring is carried by the driver and is released to bias the shield when the end of the barrel is reached (Figs. 8-11).

In reference to claim 14, Cameron discloses that the driver has two sensor elements to detect eh distal end of the barrel (the plunger has two radially extending flanges).

In reference to claim 15, Cameron discloses that the housing and the shield are equipped with latches (124/126 and 120/122).

In reference to claim 16, Cameron discloses that the latches prevent premature release of the shield (Fig. 8).

In reference to claim 17, Cameron discloses that the latches retain the shield in a needle shielded position (Fig. 10).

Response to Arguments

Applicant's arguments, see pages 8-10 of Applicant's arguments, filed 11/20/2009, with respect to the rejection(s) of claim(s) claims12-17 under Chevallier have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Cameron in view of Chevallier.

With respect to Applicants arguments against claims 1-11 and 18 and the Cameron reference, the examiner does not find these arguments persuasive. Applicant argues that the sensors 114/116 do not detect the end profile of the barrel. It is the

examiner's position, however, that Figs. 8 and 9 of Cameron disclose that 114/116 are advanced until they contact 102 which is the end profile of the barrel, and Fig. 9 specifically discloses that 114/116 contact 102 and in response to contacting 102, disengage the shield members such that it triggers activation of the shield driver. Therefore the rejection under the Cameron reference is being maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767